DOCKET NO.: ALZA-0142 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
George V. Guittard, *et al.*
Application No.: 10/645,467
Filing Date: August 20, 2003
Confirmation No.: 8204
Group Art Unit: 1616
Examiner: George, Konata M.
For: METHOD FOR MANAGEMENT OF INCONTINENCE

DATE OF DEPOSIT: **January 13, 2006**

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Wendy A. Choi

TYPED NAME: **Wendy A. Choi**
REGISTRATION NO.: **36,697**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

☐ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☒ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.116 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

- ☐ Certification in Accordance with § 1.97(e) is attached; or
- ☒ The fee of **$180.00** as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **$180.00** as set forth in § 1.17(p).

☒ Copies of reference numbers **1 through 364** listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of reference numbers on the attached Form PTO 1449 are not required to be submitted pursuant to the waiver of 37 CFR § 1.98(a)(2)(ii).

- ☐ Copies of references - are not being submitted because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application number , filed for which a claim for priority under 35 U.S.C. § 120 has been made in the instant application.

☐ The relevance of those listed references which are not in the English language is as follows:

There are no listed references which are not in the English language.

REMARKS

Pursuant to 37 C.F.R. § 1.98, the art identified in the appended documents and other information and matters discussed below may be helpful to the U.S. Patent and Trademark Office (PTO) in its consideration of the above-identified patent application.

ALZA Corporation, the assignee of this application, has filed a Request for Reexamination of claims 1 to 23 of related U.S. Patent No. 6,919,092 ("092 Patent"). This application is a continuation of Application No. 09/785,805, which issued as the 092 Patent. The reexamination of the 092 Patent was assigned to Examiner Evelyn Mei Huang, and has been granted.

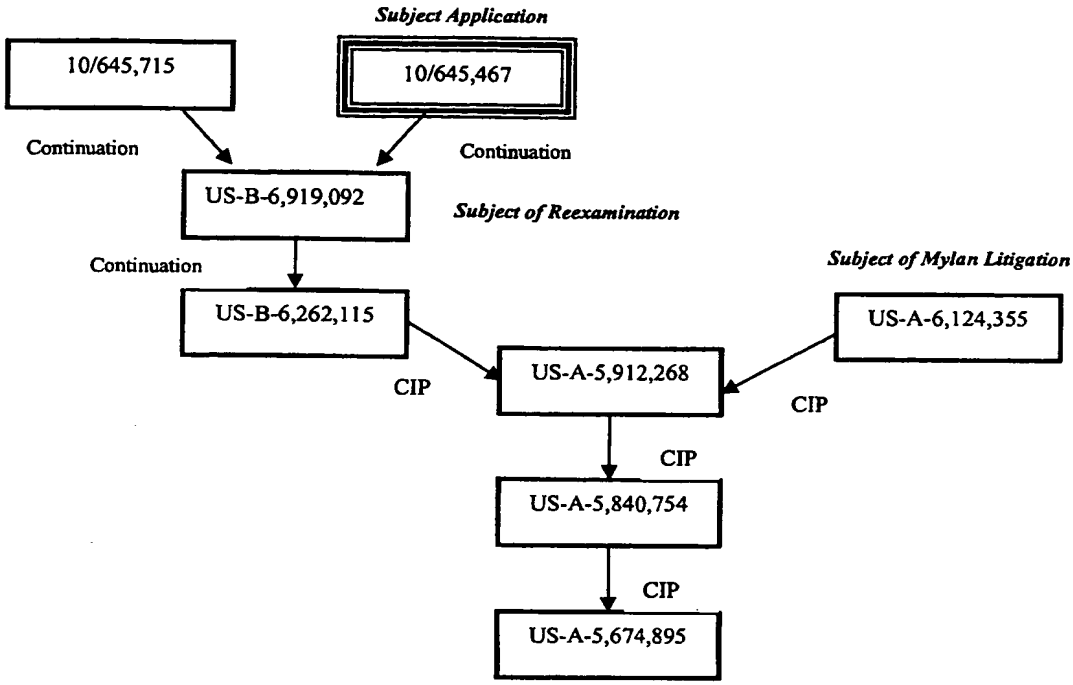
IMPAX Laboratories, Inc. and Mylan Pharmaceuticals Inc. have both filed certificates with the U.S. Food and Drug Administration, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications"), alleging that, *inter alia*, the claims of the 092 Patent are invalid either under 35 U.S.C. § 102(b) as anticipated and/or under 35 U.S.C. § 103(a) as obvious. ALZA does not agree, and believes that the references cited in the Paragraph IV Certifications, alone or in combination, do not render claims 1 to 23 of the patent unpatentable or invalid.

In addition, IMPAX alleges in its Paragraph IV Certification that ALZA engaged in

inequitable conduct for failing to identify and disclose to the Office litigations involving U.S. Patent No. 6,124,355 and certain references that are identified in the accompanying Form PTO-1449. ALZA denies that it withheld any material information with the intent to mislead the Patent Office.

U.S. Patents Nos. 5,674,895, 5,840,754, 5,912,268, 6,124,355 (the "355 Patent"), and 6,262,115, which share a claim of priority with the instant patent application, are or have been the subject of litigation, *i.e., ALZA Corporation v. IMPAX Laboratories, Inc.,* Civil Action Nos. 03-04032-VRW (N.D. Calif.), *IMPAX Laboratories v. ALZA Corporation, Inc.,* Civil Action Nos. 03-04796-VRW (N.D. Calif.) (both N.D. Calif. Cases collectively referred to as the "IMPAX Litigations"), and *ALZA Corporation v. Mylan Laboratories, Inc.*, Civil Action No. 1:03CV61 (N.D. W.Va.) ("Mylan Litigation").

The 355 Patent is a continuation-in-part of Application No. 08/806,773, filed February 26, 1997, now U.S. Patent No. 5,912,268, which is continuation-in-part of Application No. 08/706,576, filed September 5, 1996, now U.S. Patent No. 5,840,754, which is a continuation-in-part of Application 08/445,849, filed May 22, 1995, now U.S. Patent No. 5,674,895.



The only litigation to proceed to trial is the Mylan Litigation concerning the 355 Patent. Both the Mylan and IMPAX courts interpreted the 355 Patent in the same way. As discussed more fully below, a final decision has been entered in the Mylan Litigation holding the 355 Patent claims in suit invalid and not infringed, and as a result Judgment was entered in the IMPAX Litigation concerning the 355 Patent without considering the merits. The litigations concerning patents other than the 355 Patent were dismissed after ALZA granted Mylan and IMPAX covenants not to sue.

ALZA is submitting in Appendix I a Form PTO-1449 listing, *inter alia*, certain patents, printed publications, and other materials that came to the Patent Owner's attention during the above-noted litigations. A copy of each of the documents is included with the Form PTO-1449. The Examiner is requested to indicate consideration of each reference or

document with an initial in the left hand column next to each reference or document.

As is typical in a patent litigation, Mylan and IMPAX raised a wide range of different defenses relating to the scope, validity, and enforceability of the 355 Patent, all of which are vigorously disputed by ALZA, but may be relevant in some cases to the pending claims. The Court entered judgment in Mylan's and favor invalidating the 355 Patent claims in suit. During the protracted proceedings, the litigants conducted extensive discovery and there were numerous motions and memoranda filed by the litigants with respect to various issues.

To the extent not precluded by the Protective Orders entered by the respective courts in the Mylan Litigation and IMPAX Litigations, Applicants' undersigned counsel is available to immediately provide a copy of all materials generated during these litigations (note that not all constitute prior art). ALZA has made an extensive and good faith effort to present disclosure of such materials that may be relevant to the prosecution of this pending application, namely materials that may be relevant to: (1) the identification and scope of patent and printed prior art; (2) the interpretation and scope of the claims in the pending application; and (3) application of the art to the claims in the pending application.

ALZA recognizes the burden placed on the Examiner by the large volume of materials being provided pursuant to the Information Disclosure Statement. To further facilitate the Examiner's consideration of these materials, but without attempting to usurp the Examiner's opportunity to fully consider each item, ALZA has in the table in Appendix II categorized the disclosure of each document generated in the Mylan Litigation and IMPAX Litigation, which may serve as a helpful guide to direct the Examiner to certain materials that

may be relevant to specific subject matter and issues. Each document is categorized according to whether it contains a discussion or disclosure of, or reference to, one or more of the following subjects; the drug oxybutynin; controlled release delivery of drug (oxybutynin or otherwise); and Ditropan XL – naturally there is a great deal of overlap and so, to some extent, these characterizations may be partially subjective. The chart also indicates whether the document is litigation related. Finally, in the last column, where a document has been referred to in briefs and other filings submitted by the parties in the litigations, a citation is given by reference to a Tab Number. For the Examiner's convenience, the briefs and other filings referred to by Tab Number in the chart have been collected and submitted in the bound volumes accompanying this Supplemental Information Disclosure Statement.

ALZA also submits herewith the Post-Trial Memorandum Opinion and Order that the District Court recently issued in the Mylan Litigation; this document is also listed on the enclosed Form PTO-1449. Although the District Court held the claims of the 355 Patent to be invalid in view of certain references, ALZA does not believe that this holding is relevant to examination of the pending claims. Indeed, the respective claims of the 355 Patent and the above-identified patent application differ from one another, as is apparent from even a cursory review. For example, representative pending claim 32 of the above-identified patent application is directed to a method for treating involuntary incontinence by orally admitting to a patient a sustained release, once-day dosage form of 5-250 mg of oxybutynin or its salt to provide a plasma ratio of oxybutynin/desethylmetabolite greater than about 0.18. The ratio of oxybutynin/desethylmetabolite is not recited in any claim of the 355 Patent. Similarly, pending claims 33 to 43 refer to a specific range of ratios of oxybutynin/desethylmetabolite that is not recited the 355 Patent claims. Thus, although ALZA wishes to make the Post-Trial

Memorandum Opinion and Order of record for purposes of full disclosure, it is not believed to be relevant to patentability of the claims of the above-identified patent application.

ALZA respectfully requests that the Examiner indicate consideration of each reference or document with an initial in the left hand column next to each reference or document.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Date: **January 13, 2006**

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Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0142**	Application No. **10/645,467**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1616**
	Confirmation No. **8204**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	1	Data Processed Using Dissprof Program (V1.1), Oxybutynin C1, **Joint Exhibit 25, November 24, 2003** MYLAN 1014396-1014492
	2	Skelly, J.P. et al., "*In Vitro* and *In Vivo* Testing and Correlation for Oral Controlled/Modified-Release Dosage Forms", *Pharmaceutical Research,* **1990,** 7(9), 975-977, **Joint Exhibit 67**
	3	Theeuwes, F. et al., "Osmotic Delivery Systems for the β-Adrenoceptor Antagonists Metoprolol and Oxprenolol: Design and Evaluation of Systems for Once-Daily Administration, *Br. J. Clin. Pharmac.,* **1985,** 19, 695-765, **Joint Exhibit 81,**
	4	Oxybutynin, ALZA/TDC Meeting, **Friday July 15, 1993,** Palo Alto, Ca. **Defendant's Exhibits DX 00028,** DXL-016926 thru DXL-016976
	5	Ballard, B.E., "Prolonged-Action Pharmaceuticals", Chapter 91, **Defendant's Exhibit DX 00403,** 1594-1613
	6	Corrigan, O.I. et al., "Influence of Dissolution Medium Buffer Composition on Ketoprofen Release from ER Products and in Vitro—in Vivo Correlation", *International Journal of Pharmaceutics,* **2003,** 147-154, **Defendant's Exhibit DX 00408**
	7	Frick, A. et al., "Biopharmaceutical Characterization of Oral Controlled/Modified-Release Drug Products. In Vitro/in Vivo Correlation of Roxatidine", *European Journal of Pharmaceutics and Biopharmaceutics,* **1998,** 46, 313-319, **Defendant's Exhibits DX 00411**
	8	Drug Class Review on Urinary Incontinence Drugs", Final Report, **February 2003,** Oregon Health & Science University, **Defendant's Exhibit DX 00431**
	9	Oregon Health Resources Commission, Urinary Incontinence (Update Report) **Update #1, March 2004,** 12 pages, **Defendant's Exhibit DX 00432**
	9B	Ouslander, J.G. et al., "Pharmacokinetics and Clinica Effects of Oxybutynin in Geriatric Patients", *The Journal of Urology,* **1988,** 140, 47-50, **Defendant's Exhibit DX 00433**
	10	Qiu, Y. et al., "Once-a-Day Controlled-Release Dosage Form of Divalproex Sodium II: Development of a Predictive *In Vitro* Drug Release Method", *Journal of Pharmaceutical Sciences,* **November 2003,** 92(11), 2317-2325, **Defendant's Exhibit DX 00437**
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	11	ALZA Communication Exchange, A.C.E. Briefing, "The Making of Ditropan® XL: An Epic Celebrating the Cast of ALZAns who made it Happen, from 1993 to Today", **January 20, 1999,** DXL-063089 thru DXL-063100, **Defendant's Exhibit DX 00448,**
	12	Theeuwes, et al., "Elementary Osmotic Pump for Indomethacin", *Journal of Pharmaceutical Sciences,* **March 1983,** 72(3), 253-258, **Defendant's Exhibit DX 00450**
	12A	Thuroff, J.W. et al., "Randomized, Double-Blind, multicenter Trial on Treatment of Frequency, Urgency and Incontinence related to Detrusor Hyperactivity: Oxybutynin Versus Propantheline Versus Placebo", *The Journal of Urology,* **April 1991,** 145, 813-817, **Defendant's Exhibit DX 00453**
	13	Welling, P.G., "In Vitro Methods to Determine Bioavailability: In Vitro-In Vivo Correlations", 223 thru 232, **Defendant's Exhibits DX 00462**
	14	Executive Summary, OROS® (Oxybutynin Chloride) CPC-1, **October 1997,** DXL-031021 thru DXL-063202, **Defendant's Exhibit DX 01079**
	15	Stage 0: Product Concept Assessment Form Synopsis, **March 2, 1993,** DXL- 063198 thru 063202, **Defendant's Exhibits DX 01143**
	16	Ditropan Xl and Market Pricing, **Defendant's Exhibit DX 01151,** JJ-00447 thru JJ-00456
	17	Harry C. Boghician (Portfolio), 5 pages **Defendant's Exhibit DX 1216 A**
	18	In the United States District Court for the Northern District of West Virginia, ALZA Corporation, Plantiff v. Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc. Defendants, C.A. No:. 1:03CV61, Expert Report of James A. Forstner, **April 29, 2004, Defendant's Exhibit DX 01219**
	19	Curriculum Vitae-Gordon L. Amidon, **Defendant's Exhibit DX 01226,** 93 pages
	20	Fax Letter from Jeffrey I.D. Lewis to James H. Wallace, **Defendant's Exhibit DX 01245,** 2 pages
	21	Curriculum Vitae, Stanley Kandzari, M.D. **Updated April 1, 2005, Defendant's Exhibit DX 1266 B,** 1page
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	22	Experimental Formula Sheet-Sustained Release Oxybutynin Chloride Pellets, MYLAN 1014435, **Defendant's Exhibit DX 01403**
	23	Australia Patents Act, "Complete Specification for Sustained Release Pharmaceutical Composition, 55 pages
	24	Saks, S.R. MD, "Pharmacokinetics of OROS® and Oxybutynin", *ALZA Corporation Physician Advisory Board Meeting,* **October 9-11, 1998,** DXL-044580 thru 004591 **Defendant's Exhibit DX 1501**
	25	Winkler, H.A. et al., "Treatment of Detrusor Instability with Oxybutynin Rectal Suppositories" *International Urogynecology Journal,* **1998,** 9, 100-102, **Defendant's Exhibit DX 1503,** 3 pages
	26	Massad, C.A. et al., "The Pharmacokinetics of Intravesical and Oral Oxybutynin Chloride", *The Journal of Urology,* **1992,** 148, 595-597, **Defendant's Exhibit DX 1504**
	27	**Defendant's Exhibit DX 1507,** DXL084950 thru DXL084985
	28	Projected Ditropan Xl Net Trade Sales, **Defendant's Exhibit DX 1511,** 5 pages
	29	Quarterly TRX Market Share and TRX Following Launch(Quarterly), **Defendant's Exhibits DX 1512,**
	30	Gupta, S. PhD., "New Pharmacokinetic Information on Ditropan® XL, *Physician Advisory Board Meeting, Medical Education Technologies Job # AZ11-0013,* **Defendant's Exhibit DX 1515C,** DXL 045275 thru 045313
	31	Stage 0: Product Concept Assessment Form Synopsis, **March 2, 1993, Defendant's Exhibit DX 1517,** DXL 063216 thru 063222
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	32	Final Report C-96-074-02 "Effect of Food on the Pharmacokinetics and Bioavailability of OROS® (oxybutynin chloride) relative to Ditopan®", **November 1997,** DXL-081963 thru 081999, **Defendant's Exhibit DX 1530**
	33	Oxybutynin Chloride, **Defendant's Exhibit DX 1540,** DXL 050624 ,050505 thru 050516, 9 pages
	34	Oxybutynin Chlroide, **Defendant's Exhibit DX 1541,** DXL 050625, 1 page
	35	**Defendant's Exhibit DX 1542,** 1page
	36	**Defendant's Exhibit DX 1543,** ALZA Expert 00267, 1 page
	37	Genitourinary Smooth Muscle Relaxants, *American Hospital Formulary Service,* **1997, Defendant's Exhibit DX 1544,** DXL 079384 thru DXL 0793387
	38	Letter from Jeffrey I.D. Lewis to Nicholas A Peppas, Ph.D., **Defendant's Exhibits 1546,** 5 pages
	39	In the United States District Court for the Southern District of Florida, Pfizer, Inc. and Alza Corporation, Plaintiffs, v. Andrx Corporation, Andrx Pharmaceuticals, inc., and Andrx Pharmaceuticals, LLC, Defendants, C.A. No:. 01-8636, Amended Complaint, **Defendant's Exhibit DX 1548,** 17 pages
	40	Siepmann, J. et al., "HPMC-Matrices for Controlled Drug Delivery: A New Model Combining Diffusion, Swelling, and Dissolution Mechanisms and Predicting the Release Kinetics", *Pharmaceutical Research,* **1999,** 16(11), 1748-1756, **Defendant's Exhibit DX 1551**
	41	Siepman, J. et al., "A New Model Describing the Swelling and Drug Release Kinetics from Hydroxypropyl Methylcellulose Tablets", *Journal of Pharmaceutical Sciences,* **January 1999,** 88(1), 65 thru 72, **Defendant's Exhibit DX 1552**
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	42	Baker, R., "Controlled Release of Biologically Active Agents", **1987,** 1-21, **Defendant's Exhibit DX 1553**
	43	'355 Claim 1 vs. Baichwal Example 15 Data, 1 page, **Defendant's Exhibit 1554**
	44	'355 Claim 1 vs. Baichwal Example 15 vs. Example 1, 1 page, **Defendant's Exhibit 1557,**
	45	Fundamentals of Controlled Release and Pharmaceutical Engineering, **Spring 1993, Defendant's Exhibit DX 1558**
	46	'355 Claim 1 vs. '355 Example 1 Data, **Defendant's Exhibit DX 1559,** 1 page
	47	U.S. Pharmacopeia & National Formulary, **Defendant's Exhibit DX 1561,** 2232-2240
	48	Figure 1 of the '355 Patent: Typical Release Curve for 24-Hour Controlled Release Data, **Defendant's Exhibit DX 1562, 1563** 2 pages
	49	General Requirements for Tests and Assays, **Defendant's Exhibit DX 1566,** 1833 thru 1861
	49A	Moore, K. et al., "Oxybutynin Hydrochloride (3mg) in the Treatment of Women with Idiopathic Detrusor Instability", *British Journal of Urology,* **1990,** 66, 479-485, **Defendant's Exhibit DX 1570**
	50	USP Dissolution Calibrator, Non-Disintegrating Type, **Defendant's Exhibit DX 1573,** 2 pages
	51	Oxybutynin Chloride ER (OXYB-0262) Data, **Defendant's Exhibit DX 1580-DX 1586,** Mylan 0060307,1 page
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	52	Reviewer Guidance-Validation of Chromatographic Methods, *Center for Drug Evaluation and Research (CDER),* **November 1994,** 1 thru 30, **Defendant's Exhibit 1588**
	53	Drug Release Profile Data- **Defendant's Exhibit DX 1589,** MYLAN 1014490-1014492
	54	Drug Release Profile Data- **Defendant's Exhibit DX 1590,** MYLAN 1014485-1014487
	55	Drug Release Profile Data- **Defendant's Exhibit DX 1591,** MYLAN 1014477-1014479
	56	Drug Release Profile Data- **Defendant's Exhibit DX 1592,** MYLAN 1014480-1014482
	57	ALZA Corporation-Payments to Virginia Commonwealth University Data-**Defendant's Exhibit 1593,** DXL 085000-085017
	58	Mylan 10 mg Product-Apparatus 2(Paddle) with Media Switch Data-**Defendant's Exhibit DX 1594-1598**
	59	U.S. Pharmacopeia & National Formulary, **Defendant's Exhibit DX 1803,** 1128-1129
	60	Baichwal Teaches the Conventional Wisdom Data-**Defendant's Exhibit DX 1804,** 1 page
	61	Mylan 5mg Product Data-**Defendant's Exhibit DX 1805,** 7 pages
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	62	Mylan 10 mg Product Data-**Defendant's Exhibit DX 1806,** 4 pages
	63	Concentration Result Data-**Defendant's Exhibit DX 1808,** 1 page
	64	U.S. Pharmacopeia- The Official Compendia of Standards, **Defendant's Exhibit 1814,** 4 pages
	65	Mylan 10 mg Product, Mylan 5 mg Product Data- **Defendant's Exhibit DX 1816-1817**
	66	U.S. Pharmacopeia- The Official Compendia of Standards, **Defendant's Exhibit 1818,** 6-8, 2160-2165
	67	Mylan 10 mg Product Data- **Defendant's Exhibit DX 1819,** 1 page
	68	U.S. Pharmacopeia- The Official Compendia of Standards, **Defendant's Exhibit 1821,** 2513-2519
	69	Copy of CD- **Defendant's Exhibit DX 1822**
	70	'355 Claim 1 vs. Examples A and B Data- **Defendant's Exhibit 1823,** 1 page
	71	Data- **Defendant's Exhibit 1825,** 1 page
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	72	Mylan Tablet Data-**Defendant Exhibits 1827 thru 1831**
	73	5 mg Oral Solution Data-**Defendant's Exhibit 1832-1833,** 46 pages
	74	Mylan Tablet Data-**Defendant's Exhibit 1836,** 1 page
	75	Mylan Tablet Data-**Defendant's Exhibit 1900-1901**
	76	Miyamoto, E. et al., "Physico-Chemical Properties of Oxybutynin", *Analysts,* **July 1994,** 119, 1489-1492, **Defendant's Exhibit 1902,** DXL 005871-005874
	77	State of the Art: Colonic Absorption Studies, Defendant's Exhibit DX 2001, 1 page
	78	Colonic Absorption Studies and Data-**Defendant's Exhibit DX 2002**
	79	Wong, P.S.L. et al., "Osmotically Controlled Tablets", *Modified-Release Drug Delivery Technology,* **2003,** 101-114 **Joint Exhibit 109**
	80	ALZA: OROS® Oral Delivery Technology, **March 9, 2004,** http://www.alza.com/print/oros, **Joint Exhibit 111,** 2 pages
	81	Patent Information: DITROPAN XL®(oxybutynin chloride) Extended Release Tablet, **Joint Exhibit 112,** DXL 070943
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant *(Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0142**	Application No. **10/645,467**
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	82	Douchamps, J. et al., "The Pharmacokinetics of Oxybutynin in Man", *Eur J. Clin Pharmacol,* **1988,** 35, 515-520, **Joint Exhibit 116,** 5 pages
	83	Cystrin® SR, Sustained Release Oxybutynin Hydrochloride, Development Pharmaceutics, **March 9, 1994,** PW 000225-PW 000280, **Joint Exhibit 130**
	84	Patent Data, DXL 070941-070942, **Joint Exhibit 131**
	85	The United States Pharmacopeia Convention, Inc. **1990,** 1790-1799, **Joint Exhibit 133**
	86	Oxybutynin/Official Monographs, **Joint Exhibit 134,** 1 page
	87	The United States Pharmacopeia Convention, Inc., The Official Compendia of Standards, **2002,** 2010-2022, **Joint Exhibit 135**
	88	**Joint Exhibit 137,** 1578-1581
	89	Van Bommel, E.M.G. et al., "Comparison of *In Vitro and In Vivo* Release Characteristics of Acetaminophen from Gradient Matrix Systems, *Biopharmaceutics & Drug Disposition,* 1991, 12, 367-373, **Joint Exhibit 139**
	90	Oxybutynin Chloride Extended-Release Tablets, 10 MG, Uniformity of Dosage Units (FP-OXYB10-CU-M) , 5514-5539, MYLAN 0065620-0065646, **Joint Exhibit 232**
	91	Preik, M. et al., "Effect of Controlled-Release Delivery on the Pharmacokinetics of Oxybutynin at Different Dosages: Severity-Dependent Treatment of the Overactive Bladder", *BJU International,* 2004, 821-827, **Plaintiff's Exhibit 396**
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	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1616**
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	Filing Date **August 20, 2003**	Group **1616**
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	323	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Motion for Summary Judgment (#5) of Invalidity Based Upon a Lack of Novelty over the Prior Art, Memorandum in Support of Mylan's Motion for Summary Judgment (#5) of Invalidity Based upon a Lack of Novelty over the Prior Art, **July 14, 2004**
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	335	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Alza's Combined Memorandum in Opposition to Defendant's Motion for Summary Judgment on the Threshold Priority Issue (#1) and Invalidity based on Inherent Anticipation, **August 20, 2004,** with attached Exhibits A,B
	336	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Reply Memorandum in Support of Its Motion for Summary Judgment (#2) of Invalidity Based on Inherent Anticipation, **September 3, 2004**
	337	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Plaintiff Alza Corporation's Memorandum in Reply to Defendant's Responsive Claim Construction Memorandum, **September 7, 2004**
	338	In the United States District Court for the Northern District of West Virginia, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Supplemental Briefing on *Kennecott* and Alleged "Inherent Written Description", **November 2, 2004**
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0142**	Application No. **10/645,467**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1616**
	Confirmation No. **8204**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	339	In the United States District Court for the Northern District of West Virginia, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Alza'a Memorandum in Response to Mylan's Supplemental Briefing on *Kennecott* and Alleged "Inherent Written Description", **November 13, 2004**
	340	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Plaintiff's Pre-Trial Memorandum, **December 22, 2004**
	341	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Memorandum in Support of its Motion for Reconsideration, **December 23, 2004**
	342	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Motion for Reconsideration of the Court's Ruling on Summary Judgments # 1 and #2, **December 24, 2004**
	343	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Motion for Reconsideration of the Court's Ruling on Summary Judgments #1 and #2, Mylan's Memorandum in Support of its Motion for Reconsideration, **January 24, 2005**
	344	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Reply Memorandum in Support of its Motion for Reconsideration, **January 31, 2005**
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0142**	Application No. **10/645,467**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1616**
	Confirmation No. **8204**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	346	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Plaintiff's Post Trial Memorandum(Corrected) **June 1, 2005**
	347	Ditropan XL NTS: Projections and Annuals, **Defendant's Exhibit DX 2012**
	348	Letter from Michael B. Chancellor, M.D. to Richard McCormick-Re: ALZA v. Mylan [Ditropan XL], **Defendant's Exhibit DX 2016**
	349	Quarterly TX Market Share (Updated) , **Defendant's Exhibit DX 2017**
	350	Market Share Trends, **Defendant's Exhibit DX 2018**
	351	J & J Worldwide Advertising Group media Budget Control Record(MBCR), Ditropan, **Defendant's Exhibit DX 2019**
	352	DX 2020-Articles teaching that a Lower Dose of Oxybutynin is Effective and has Fewer Side Effects, **Defendant's Exhibit DX 2020**
	353	Ditropan XL: BMEs as a Percent of Net Trade Sales, **Defendant's Exhibit DX 2024**
	354	Alza Corporation Physician Advisory Board Meeting, Phoenix, AZ, **1998, Defendants Exhibit DX 2029**
	355	Ditropan-Xl TRX Market Share Compared to Rebates (%NTS), **Defendants Exhibit DX 2025**
	356	Chancellor, M.B. MD., "What is Really New in Overactive Bladder?, **February 25, 2004, Defendant's Exhibit DX 2038**
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0142**	Application No. **10/645,467**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1616**
	Confirmation No. **8204**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	357	AWP Price Per Day: TID Oxy Products, **Defendant's Exhibit's DX 2039**
	358	Ditropan ® Xl, Recommendation for Additional Clinical Study, **Defendant's Exhibit 2056,**
	359	Ditropan XL: NTS Compared to Profits, **Defendant's Exhibit DX 2061**
	360	Ditropan XL Profits Compared to J & J Investment, **Defendant's Exhibit DX 2062**
	361	Ditropan XL Financial Data, **Defendant's Exhibits DX 2063**
	362	Ditropan-XL TRX Market Share Compared to BME/Selling (%NTS), **Defendant's Exhibits DX 2065**
	363	Ditropan Xl ® vs Detrol ® Spit Study, Post-Launch (Stage 5), **Defendant's Exhibit DX 2067**
	364	Physicians' Desk Reference, PDR®, 42 Edition, **1988,** Ditropan Tablets and Syrup

EXAMINER	**DATE CONSIDERED**